CLAIMS

What is claimed is:

1. An *in vitro* method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, the method comprising:

a) contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium sufficient to initiate clotting, and APC in a test reaction; and

b) comparing the clotting time for the test reaction to the clotting time for a control reaction carried out under the same conditions as the test reaction, but with a control sample comprising a coagulation factor V or Va-containing specimen from an individual not having or not at risk of having a thrombotic disorder associated with APC-resistant factor V or Va, wherein:

i) detection of a decreased clotting time in the test reaction relative to the control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va; and

ii) detection of a similar clotting time in the test reaction relative to the control reaction indicates that the subject does not have or is not at risk of developing a thrombotic disorder associated with APC-resistant factor V or Va.

identical to claim 1 of Pat 5,834,223

101 double patenting